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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,310	05/12/2006	Jorgen Carlsson	102821-202	6946
27267	7590	10/30/2009	EXAMINER	
WIGGIN AND DANA LLP			SWARTZ, RODNEY P	
ATTENTION: PATENT DOCKETING				
ONE CENTURY TOWER, P.O. BOX 1832			ART UNIT	PAPER NUMBER
NEW HAVEN, CT 06508-1832			1645	
			MAIL DATE	DELIVERY MODE
			10/30/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/563,310	CARLSSON ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Rodney P. Swartz, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 August 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-3,5-41,47,49,52-56,58 and 59 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-3,5-41,47,49,52-56,58 and 59 is/are rejected.  
 7) Claim(s) 28 and 29 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 8/13/09.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Applicants' Response to Office Action, received 13 August 2009, is acknowledged. Claims 1, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 28, 29, 30, 31, 33, 34, 35, 36, 37, 38, 39, 41, 52 and 54 have been amended. Claims 4, 42, 43, 44, 51 and 57 have been cancelled. New claims 58 and 59 have been added.

2. Claims 1-3, 5-41, 47, 49, 52-56, 58 and 59 are pending and under consideration.

**Rejections Moot or Withdrawn**

3. The rejection of claims 4, 51 and 57 under 35 U.S.C. 112, second paragraph, as being indefinite for "related to", is moot in light of the cancellation of the claims.

4. The rejection of claims 4, 51 and 57 under 35 U.S.C. 112, second paragraph, as being indefinite for "corresponds to", is moot in light of the cancellation of the claims.

5. The rejection of claims 51 and 57 under 35 U.S.C. 112, second paragraph, as being indefinite for positions of mutations, is

6. The rejection of claim 51 under 35 U.S.C. 112, second paragraph, incomplete steps, is moot in light of the cancellation of the claim.

7. The rejection of claims 1-3, 5-41, 47, 49 and 52-56 under 35 U.S.C. 112, second paragraph, as being indefinite for "related to", is withdrawn in light of the amendment of the claims.

8. The rejection of claims 1-3, 5-32, 34-41, 47, 49 and 52-56 under 35 U.S.C. 112, second paragraph, as being indefinite for "corresponds to", is withdrawn in light of the amendment of the claims.

9. The rejection of claims 1-3, 21, 24-41, 47, 49 and 52-56 under 35 U.S.C. 112, second paragraph, as being indefinite for positions of mutations, is withdrawn in light of the amendment of the claims.

10. The rejection of claims 5 and 6 under 35 U.S.C. 112, second paragraph, as being indefinite for improperly broadening of scope of claim, is withdrawn in light of the amendment of the claims.

11. The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite for "claim 4 4-9" is withdrawn in light of the amendment of the claim.

12. The rejection of claim 19 under 35 U.S.C. 112, second paragraph, as being indefinite for "as set out in" is withdrawn in light of the amendment of the claim.

13. The rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being indefinite for "as set in" is withdrawn in light of the amendment of the claim.

14. The rejection of claim 22 under 35 U.S.C. 112, second paragraph, as being indefinite for "as set forth in", and lacking a verb, is withdrawn in light of the amendment of the claim.

15. The rejection of claims 25-28 under 35 U.S.C. 112, second paragraph, as being indefinite for "additional amino acid residues" is withdrawn in light of the amendment of the claims.

16. The rejection of claims 28-37 under 35 U.S.C. 112, second paragraph, as being indefinite for "optionally further", is withdrawn in light of the amendment of the claims.

17. The rejection of claim 37 under 35 U.S.C. 112, second paragraph, as being indefinite for "fragment" is withdrawn in light of the amendment of the claim.

18. The rejection of claim 38 under 35 U.S.C. 112, second paragraph, as being indefinite for improper broadening of claim scope, is withdrawn in light of the amendment of the claim.

19. The rejection of claim 41 under 35 U.S.C. 112, second paragraph, as being indefinite for "ADEPT", is withdrawn in light of the amendment of the claim.
20. The rejection of claim 23 under 35 U.S.C. 112, second paragraph, as being indefinite for reference sequence is withdrawn in light of the amendment of the claims.

### **Rejections Maintained**

21. The rejection of claim 33 under 35 U.S.C. 112, second paragraph, as being indefinite for "corresponds to", is maintained for reasons of record.

Applicants argue that the claim amendments obviate the rejection.

The examiner has considered applicants' argument, but does not find it persuasive because claim 33 retains the phrase "corresponds to".

22. The rejection of claim 55 under 35 U.S.C. 112, second paragraph, as being indefinite for "positive" and "negative" slides, is maintained.

Applicants argue that a person skilled in the art would readily understand that a positive control is a procedure very similar to the actual experimental text, but which is known from previous experience to give a positive result. On the other hand, a negative control is a procedure known to give a negative result.

The examiner has considered applicants' argument, but does not find it persuasive. The argument is drawn to a procedure, but the instant claim is drawn to a product, i.e., tissue slides labeled positive and negative control. Since the kit is for diagnosis of HER2 "overexpression" in a tissue sample, it remains unclear what is considered a positive and a negative control, i.e., what levels are considered a positive overexpression and what is considered a negative overexpression of HER2.

### **Claim Objections**

23. Claims 28 and 29 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

24. Claims 1-3, 5-41, 47, 49, 52-56, 58 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claims 1, 21 and 34 now recite a sequence "derived from" a domain. the specification does not define the metes and bounds of such a "derivation". Thus, the claims are indefinite.

Claims 2, 3, 5-20, 22-33, 35-41, 47, 49, 52-56, 58 and 59 depend from the claims, but do not clarify the issue.

### **Conclusion**

25. No claims are allowed.

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of

the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

October 30, 2009